K071437 pg 1 of 2

KARL STORZ ENDOSCOPY

## 510(k) SUMMARY

**Sponsor/Submitter:** Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone: (310) 338-8100
Fax: (310) 410-5519

SEP 12 2007

**Contact Person:** Crystal Dizol
Regulatory Affairs Associate
Email: cdizol@ksea.com

**Date of Submission:** May 17, 2007

**Device Trade Name:** KSEA MegaFix®-C Bioabsorbable Composite Interference Screw

**Common Name:** Bioabsorbable Composite Interference Screw

**Classification Name:** Screw, Fixation, Bone

**Regulation Number:** 21 CFR 888.3040

**Product Code:** HWC

**Predicate Device(s):** KSEA MegaFix® (K013107)
Sciences for Biomaterials Ligafix® (K061262, K050407)
Conmed Linvatec Biomaterials Matryx™ (K063588, K052080)
DePuy Mitek Milagro (K060830)

**Device Description:** The KSEA MegaFix®-C Bioabsorbable Composite Interference Screw is a one-time use biodegradable implant, provided to the end user in a sterile condition, and intended for interference fixation of grafts in human cruciate ligament reconstruction. The device is a bioabsorbable composite interference screw which utilizes lactide polymer composite technology to perform the intended use.

**Indications for Use:** The KSEA MegaFix®-C Bioabsorbable Composite Interference Screw is indicated for use for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

**Technological Characteristics:** The KSEA MegaFix®-C Bioabsorbable Composite Interference Screw and its predicate devices are threaded bone fixation screws that provide primary anchorage of tendon transplants until absorbed.

**Summary of Substantial Equivalence:**

The KSEA MegaFix®-C Bioabsorbable Composite Interference Screw and its predicate devices are one-time use biodegradable implants, provided to the end user in a sterile condition, and intended for interference fixation of grafts in human cruciate ligament reconstruction. The minor differences between the KSEA MegaFix®-C Bioabsorbable Composite Interference Screw and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function, or intended use of the devices. For a comparison between the KSEA MegaFix®-C Bioabsorbable Composite Interference Screw and the predicate devices, refer to the substantial equivalence chart (see below).

## Substantial Equivalence Table for KSEA MegaFix®-C Bioabsorbable Composite Interference Screw

| Device | Material | Dimensions (mm) | Design | Use | Intended Use |
|---|---|---|---|---|---|
| KSEA MegaFix®-C | poly-(L-co-D,L-lactide) 70/30/β-TCP | Diameters: 7-9<br>Lengths: 19-28 | Threaded Screw | Single Use | For use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction. |
| KSEA MegaFix® (K013107) | poly-(L-co-D,L-lactide) 70/30 | Diameters: 7-9<br>Lengths: 19-28 | Threaded Screw | Single Use | For use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction. |
| Sciences for Biomaterials Ligafix® (K061262, K050407) | polylactic acid/β-TCP | Unavailable | Threaded Screw | Single Use | For use in anterior cruciate ligament reconstruction to provide interference fixation of grafts. |
| Conmed Linvatec Biomaterials Matryx™ (K063588, K052080) | poly-(L-co-D-lactide)/β-TCP | Diameters: 7.3-9<br>Lengths: 20-30 | Threaded Screw | Single Use | For use in interference fixation of bone – patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions. |
| DePuy Mitek Milagro (K060830) | poly-(lactide-co-glycolide)/β-TCP | Diameters: 7-12<br>Lengths: 23-35 | Threaded Screw | Single Use | For the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. Also for medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Karl Storz Endoscopy-America, Inc.
c/o Ms. Crystal Dizol
Regulatory Affairs Associate
600 Corporate Pointe
Culver City, CA. 90230-7600

SEP 12 2007

Re: K071437
Trade/Device Name: KSEA MegaFix®-C Bioabsorbable
Composite Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 17, 2007
Received: June 19, 2007

Dear Ms. Dizol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

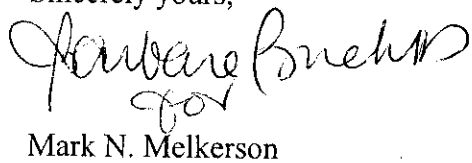
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number (if known): K071437

Device Name: KSEA MegaFix®-C Bioabsorbable Composite Interference Screw

Indications for Use: The KSEA MegaFix®-C Bioabsorbable Composite Interference Screw is intended for use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

Prescription Use: X AND/OR Over-The-Counter Use: X/O
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071437